Introduced by Senator Figueroa

February 17, 2004

An act to amend Sections 4160, 4163, 4164, 4165, and 4166 of, to repeal Section 4162 of, and to repeal and add Section 4161 of, the 4043, 4160, 4164, 4165, 4166, and 4400 of, to amend, repeal, and add Section 4163 of, to add Sections 4021.5, 4034, 4126.5, 4163.5, and 4168 to, to add and repeal Section 4169 of, and to repeal and add Sections 4161 and 4162 of, the Business and Professions Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, as amended, Figueroa. Wholesalers and manufacturers of dangerous drugs and devices.

(1) Existing law, the Pharmacy Law, provides for the licensing and regulation of wholesalers of dangerous drugs or dangerous devices by the Pharmacy Board. Existing law makes the a violation of the Pharmacy Law a crime. Existing

This bill, on and after January 1, 2007, would require a pedigree, as defined, to accompany each distribution of a dangerous drug, except that the California State Board of Pharmacy is authorized to the extend the compliance date to January 1, 2008, under specified circumstances. It would, on and after that date, prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug or device without a pedigree, and would prohibit a wholesaler or pharmacy from acquiring a dangerous drug or device without receiving a pedigree.

(2) Existing law prohibits a person from acting as a wholesaler of dangerous drugs or devices without a license.

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This bill would require dangerous drugs or dangerous devices to be acquired from a person authorized by law to possess or furnish them. The bill would exempt a licensed drug manufacturer that only ships drugs of its own manufacture from the provisions governing wholesalers, except for the prohibition against furnishing dangerous drugs or devices to an unauthorized person.

(3) Existing law imposes certain licensing and registration requirements on out-of-state manufacturers and wholesalers doing business in this state, and on their principals.

This bill would delete these requirements. The bill *instead* would make a wholesaler *person* located outside the state that ships, mails, or delivers dangerous drugs or dangerous devices into this state a nonresident wholesaler. The bill would require a nonresident wholesaler to meet specified licensing and reporting requirements, to comply with lawful directions and requests for information, to maintain a record records in readily retrievable form of dangerous drugs or dangerous devices sold, traded, or transferred to persons in this state, and to designate an exemptee-in-charge to be responsible for compliance with laws governing wholesalers.

(4) Existing law requires any manufacturer who sells or transfers a dangerous drug or dangerous device into this state or who receives a dangerous drug or dangerous device from a person in this state to, upon request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer. Existing law makes a manufacturer who fails or refuses to comply with that request subject to a citation and a fine, an order of abatement, or both.

This bill would instead would apply these provisions to a wholesaler licensed by the board. The bill would delete the provision that makes the failure or refusal to comply with a request subject to a citation and a fine, an order of abatement, or both. The bill would require a wholesaler to submit a surety bond of \$100,000, or an equivalent means of security, for each site to be licensed.

(5) The bill would prohibit a county or municipality from issuing a business license for an establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board.

The bill would prohibit a person or entity from purchasing, trading, selling, or transferring a dangerous drug or device under specified circumstances, including if he or she knew or reasonably should have

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known the drug or device was adulterated or misbranded. The bill would make a violation of those provisions subject to a specified fine.

The bill would specify to whom a pharmacist may furnish dangerous drugs.

- (6) Because a violation of the requirements and prohibitions created by this bill would be a crime, the bill would impose a state-mandated local program.
- (7) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- SECTION 1. Section 4021.5 is added to the Business and 1 Professions Code, to read:
- 4021.5. (a) "Closed pharmacy" means a pharmacy that purchases dangerous drugs for a limited patient population and that is not open for dispensing dangerous drugs to the general population.
 - (b) It is the intent of the Legislature to enact reasonable "due diligence" requirements for wholesalers supplying a closed pharmacy.
- 10 *SEC.* 2. Section 4034 is added to the Business and Professions Code. to read: 11
- 4034. (a) "Pedigree" means a record, in written or electronic form, containing information regarding each transaction involving a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until 16 final sale to a pharmacy or other person furnishing, administering,
- or dispensing the dangerous drug. 17

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- (b) A pedigree shall include all of the following information:
- (1) The source of the dangerous drug, including the name, state 19 20 license number, including California license number if available,
- and principal address of the source.

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(2) The quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

- (3) The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.
- (4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.
- (c) This section shall become operative on January 1, 2007. SEC. 3. Section 4043 of the Business and Professions Code is amended to read:
- 4043. "Wholesaler" means and includes—every a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, or agent, including a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.
- SEC. 4. Section 4126.5 is added to the Business and Professions Code, to read:
- 4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:
- (1) The wholesaler or manufacturer from whom the dangerous drug was purchased.
 - (2) A licensed reverse distributor.
- (3) Another pharmacy or wholesaler to alleviate temporary shortages that could result in the denial of health care.
 - (4) A patient.
- (5) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
- (b) Notwithstanding any other provision of law, a violation of this section by either a closed pharmacy or a person engaged in a prohibited transaction with a closed pharmacy may subject the persons who committed the violation to a fine not to exceed the

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amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

- (c) For notifications made on and after January 1, 2005, the Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the 10 Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.
 - SEC. 5. Section 4160 of the Business and Professions Code is amended to read:
 - 4160. (a) No person shall A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
 - (b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
 - (c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.
 - (d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. Each A wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.
 - (e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.
 - (f) A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships dangerous drugs of its own manufacture is exempt from this section.

39 SEC. 2.

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1 SEC. 6. Section 4161 of the Business and Professions Code is 2 repealed.

SEC. 3.

- *SEC.* 7. Section 4161 is added to the Business and Professions 5 Code, to read:
 - 4161. (a) A wholesaler *A person* located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler for purposes of this chapter.
 - (b) A nonresident wholesaler shall be licensed by the board.
 - (c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler. Each license shall be renewed annually and shall not be transferable.
 - (d) A nonresident wholesaler An applicant for a nonresident wholesaler license shall disclose to the board the names, locations, and titles of each of the following:
 - (1) Its agent for service of process in this state.
 - (2) Principal Its principal corporate officers, as specified by the board, if any.
 - (3) General Its general partners, as specified by the board, if any.
 - (4) Its owners, if the applicant is not a corporation or partnership.
 - (e) A report containing the information in subdivision (d) shall be made within 30 days of any change of office ownership, office, corporate officer, or partner.
 - (f) A nonresident wholesaler shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board pursuant to this section.
 - (g) A nonresident wholesaler shall maintain a record records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, and the record shall be so that the records are in a readily retrievable form.
 - (h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license

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in this state shall include a license verification from the licensing authority in the applicant's state of residence.

- (i) The board shall may not issue or renew a nonresident wholesaler license until the nonresident wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of the exemptee-in-charge.
- (j) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers.—Each A nonresident wholesaler shall designate and notify the board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge.
- (k) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.
- 17 (*l*) The registration fee shall be the fee specified in subdivision 18 (f) of Section 4400.

SEC. 4.

 SEC. 8. Section 4162 of the Business and Professions Code is repealed.

SEC. 5.

- SEC. 9. Section 4162 is added to the Business and Professions Code, to read:
- 4162. (a) A wholesaler that applies to the board for a wholesaler license or the renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000) for each site to be licensed, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.
- (b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine, or costs become final. The board may make a claim against the bond or security until one year after the license ceases to be valid, or until 60 days after the conclusion of any authorized administrative or legal proceeding, including an appeal, that involves the licensee, whichever occurs later.

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SEC. 10. Section 4163 of the Business and Professions Code 1 is amended to read:

- 4163. (a) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.
- (b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.
- (c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, 10 that is enacted before January 1, 2007, deletes or extends that date. SEC. 6.
- SEC. 11. Section 4163 is added to the Business and 14 Professions Code, to read:
- 4163. (a) A manufacturer or wholesaler may not furnish a 16 dangerous drug or dangerous device to an unauthorized person.
 - (b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.
 - (c) A wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug or dangerous device without providing a pedigree.
 - (d) A wholesaler or pharmacy may not acquire a dangerous drug or dangerous device without providing a pedigree.
 - (e) This section shall become operative on January 1, 2007.
 - SEC. 12. Section 4163.5 is added to the Business and Professions Code, to read:
 - 4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Section 4163 until January 1, 2008, if it determines that manufacturers, wholesalers, or pharmacies require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of
- Division 3 of Title 2 of the Government Code. SEC. 13. Section 4164 of the Business and Professions Code 37 38 is amended to read:
- 4164. All wholesalers A wholesaler licensed by the board that 39 distribute distributes controlled substances, dangerous drugs, or

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dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

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- SEC. 14. Section 4165 of the Business and Professions Code is amended to read:
- 4165. Any A wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, 10 furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

SEC. 8.

- SEC. 15. Section 4166 of the Business and Professions Code 15 is amended to read:
 - 4166. (a) Any wholesaler that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.
 - (b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

SEC. 9.

- SEC. 16. Section 4168 is added to the Business and Professions Code, to read:
- 4168. A county or municipality may not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board. For purposes of this section, an "establishment" is the licensee's physical location in California.
- 33 SEC. 17. Section 4169 is added to the Business and 34 Professions Code, to read:
 - 4169. (a) A person or entity may not do any of the following:
- (1) Purchase, trade, sell, or transfer dangerous drugs or 36
- 37 dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy, in violation
- of Section 4163.

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(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

- (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as set forth in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
- (4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.
- (5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.
- (b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.
- (c) The Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax funds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.
- (d) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date. SEC. 18. Section 4169 is added to the Business and

Professions Code, to read:

- 4169. (a) A person or entity may not do any of the following:
- (1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.
- (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

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(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as set forth in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

- (4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.
- (5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.
- (b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.
- (c) The Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax funds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.
- (d) This section shall become operative on January 1, 2007. SEC. 19. Section 4400 of the Business and Professions Code is amended to read:
- 4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:
- (a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400).
- (b) The fee for a nongovernmental pharmacy or medical device retailer annual renewal shall be one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250).
- (c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars (\$155) and may be increased to one hundred eighty-five dollars (\$185).
- 38 (d) The fee for regrading an examination shall be seventy-five dollars (\$75) and may be increased to eighty-five dollars (\$85). If

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an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

- (e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars (\$115) and may be increased to one hundred fifty dollars (\$150).
- (f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).
- (g) The fee for a hypodermic license and renewal shall be ninety dollars (\$90) and may be increased to one hundred twenty-five dollars (\$125).
- (h) The fee for application and investigation for an exemptee license under Section 4053 shall be seventy-five dollars (\$75) and may be increased to one hundred dollars (\$100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars (\$100).
- (i) The fee for an exemptee license and annual renewal under Section 4053 shall be one hundred ten dollars (\$110) and may be increased to one hundred fifty dollars (\$150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars (\$150), for renewal one hundred ten dollars (\$110), which may be increased to one hundred fifty dollars (\$150), and for filing a late renewal fifty-five dollars (\$55).
- (j) The fee for an out-of-state drug distributor's a nonresident wholesaler's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).
- (k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).
- (*l*) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.
- (m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars (\$165) and may be increased to one hundred seventy-five dollars (\$175).

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(n) The fee for an intern license or extension shall be sixty-five dollars (\$65) and may be increased to seventy-five dollars (\$75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars (\$20).

- (o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.
- (p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars (\$30).
- (q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars (\$60) and may be increased to one hundred dollars (\$100).
- (r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.
- (s) The fee for any applicant for a clinic permit is three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250) for each permit.
- (t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50). The biennial renewal fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50).
- (u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars (\$400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars (\$250).
- 36 (v) The fee for issuance of a retired license pursuant to Section 37 4200.5 shall be thirty dollars (\$30).
 - SEC. 20. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or

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- school district will be incurred because this act creates a new crime
- or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the

- 6 California Constitution.